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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/082,112 05/20/98 MENDOZA

A MSU4.1-406

EXAMINER

HM22/0212

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OKEMOS MI 48864

TURNER, S

ART UNIT

PAPER NUMBER

26

1647

DATE MAILED:

02/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/082,112

Applicant(s)

Mendoza

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit

1647



☒ Responsive to communication(s) filed on 12-4-00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 16-25 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 16-25 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Amendment

1. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.
2. The declaration and request for reconsideration filed 12-4-00 have been entered into the record and have been fully considered.
3. Claims 16-25 are pending.

Rejections Maintained

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 21 stands rejected as set forth in Paper No. 23, mailed 11-7-00 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of ATCC 74446. Specifically, amendment of the specification to recite the date of deposit is required. Further, the examiner notes that the paragraph at p. 5, line 23 remains drawn to ATCC 58643 and should be corrected to be consistent with ATCC 7446.

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Applicant's attention is directed to In re Lundack, 773F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR § 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16-25 are rejected under 35 U.S.C. 103(a) as set forth in Paper No. 26, mailed 11-7-00 as being unpatentable over Mendoza et al, J. Mycol. Med, 1996, 6:151-164, Mendoza et al, Mycopathologica, 1992(a), 119:89-93, (IDS: Ref. AI), Mendoza et al, J. Clin. Microbiology, Nov. 1992(b), p. 2980-83, Panella et al, Cancer Res., 50(14):4429-35, Sigma Catalog, p.1874, 1992 and Amicon Catalog, p. 35, 1993.

Applicants argue that the Office Action make incorrect technical assertions, that dialysis and centrifugation are equivalent, that in patent law humans are different from lower mammals unless there is a standard test which relates the two mammals and that no such relationship has been established by the examiner or in the art. Applicants further submit a Declaration under 37 C.F.R. 1.132 to the above assertions.

Applicants arguments and declaration filed 12-4-00 have been fully considered but are not persuasive because the prior art references disclose the vaccine mixture of applicants claims *comprising* intracellular and extracellular proteins, see in particular Mendoza et al., 1996, p. 159,

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column 2, lines 15-18, and Mendoza et al., 1992(a) or Mendoza et al., 1992(b) for comparisons of the cell-mass vaccine and soluble concentrated antigen vaccines, in particular Mendoza et al., 1992(a), Vaccine preparation, pp. 90-91 and Mendoza et al., 1992(b), Materials and Methods, p 2980-2981. Each of these vaccines, including the supplementation of the 28-32 kd proteins, the CMV vaccine and the SCAV vaccine *comprise* intracellular and extracellular proteins.

Applicants declaration concedes that the peptides are made intracellularly and thus support the examiners assertion that intracellular and extracellular peptides are *comprised* in the vaccine.

Secondary or tertiary structure of the recited peptides is not an element of the claimed invention.

The process limitations of ultracentrifugation through a PM-10 membrane to remove small peptides and impurities as set forth previously does not appear to result in a patentably

distinguishable product from that of dialysis to remove small peptides and impurities as the molecular weight cut offs for the PM-10 membrane and a dialysis membrane are similar as

evidenced by Sigma and Amicon and Mendoza et al., 1992(b) as set forth at p. 8-9 of the office

action of 11-7-00. The previous office action sites Sigma for dialysis tubing with a molecular weight cutoff of approximately 12,400 MW and PM-10 membrane of MW cut-off of 10,000

MW. The examiner provides herein the MW of Thimerosal as evidenced by Sigma, p. 952 of 404.8 MW and thus it is clear that Thimerosal would be removed by either dialysis or

ultracentrifugation through a PM-10 membrane. Mendoza 1996, 1992(a) and 1992(b) establishes

a similar relationship between the infectious organisms, pathogenesis, evoked immune response

(immunodominant epitopes) and serodiagnosis of P. Insidiosum in horses and humans as

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disclosed in the prior art references. In addition Mendoza 1996 discloses a recognition in the art of standard immunodiagnostic tests which similarly relate P. Insidiosum infection in humans and horses. Thus, in contrast to applicants assertion, the art recognizes a similarity in horses and humans in Pythiosis infection. Thus, as previously set forth, the skilled artisan would have an expectation of success in immunization of humans with the equine vaccine.

Status of Claims

8. No claims are allowed.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
February 8, 2001

CHRISTINE J. SAUD
PRIMARY EXAMINER
Christine J. Saud